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ABSTRACT

This paper describes selected settings, circumstances, problems, and barriers to research in Indian country, and suggests ways to mitigate or overcome such problems and barriers. Examples are drawn from four research projects. Distinctions are drawn among sponsors of research in Indian country (usually federal agencies); consumers of such research (sponsors, Congress, universities, and other research institutions); and stakeholders (sponsors, consumers, tribes, and national and regional Native organizations). Federal agencies sponsoring research in Native communities and the types of research sponsored are discussed. Sampling issues are especially problematic, given the diversity of tribes and their geographic dispersion. Problems and approaches to identifying a sample frame and drawing a representative sample are examined. Emerging tribal influence on research in Indian country is discussed, along with typical tribal requirements of researchers. Five such requirements are detailed: hiring tribal members to assist in research activities; demonstrating how findings will benefit the tribe and tribal members; guaranteeing that the research protocol does no harm to the tribe, its members, or the environment; guaranteeing confidentiality or anonymity; and publishing results only after tribal review and approval. The processes involved in obtaining three levels of approval for research are described: approvals by institutional review boards, the Office of Management and Budget (OMB), and the tribe. Ethical dilemmas confronting researchers in Indian country are discussed. (SV)

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Research in Indian Country: Challenges and Changes

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ED 473 271

Abstract

Selected settings, circumstances, problems, and barriers to research in Indian Country are described and ways to mitigate or overcome these problems and barriers are discussed. The reemergence of Indian self-determination and self-governance, federal requirements for review of research by institutional review boards (IRBs), and the Office of Management and Budget (OMB) have greatly affected the ways research is conducted in Indian Country. Tribes are gaining increasing influence over setting research agendas and funding priorities, and have, at a minimum, the power to reject unwanted research on their lands. Increasingly, researchers are required to identify and justify to concerned tribes the costs, benefits, and risks associated with participation in a study.

This paper describes selected settings, circumstances, problems, and barriers to research in Indian Country[1], and suggests ways to mitigate or overcome these problems and barriers. Examples of issues, problems, and approaches taken from actual research projects are presented in four text boxes distributed throughout this paper.

Background

Stakeholders of Research in Indian Country

The distinction among sponsors, consumers, and stakeholders of research in Indian Country is central to the theme of this paper. The primary *sponsor* of research in Indian Country is the federal government, with research generally conducted for or by federal agencies. These agencies may conduct the research directly using their own staffs. More often, however, agencies fund the research, which is conducted, under contract, by other entities and organizations. The *consumers* of research conducted in Indian Country include the organizations conducting the research, the sponsoring agencies, Congress, universities, and other research institutions. In recent years, consistent with the principles of Indian self-determination and self-governance, sponsors of research in Indian Country have started to relate to Indian tribes and Alaska Native villages (and related organizations) as consumers of the research findings. *Stakeholders* of research in Indian Country include sponsors, consumers, tribes, Alaska Native villages, their members, tribal consortia, Indian organizations, and Indian people who are not members of a tribe.

Because there are more than 550 Indian tribes and Alaska Native villages within the United States, national and regional associations, organizations, and consortia represent important stakeholders of research in Indian Country, especially research that includes or affects more than one tribe. These Indian organizations are often organized around a particular area of interest. Examples include the National Congress of American Indians (NCAI), the National Indian Health Board (NIHB), the National Indian Education Association (NIEA), and the American Indian

[1]Throughout this paper, *Indian Country* refers to any lands owned by American Indian tribes, Alaska Native villages, and consortia of tribes or Native villages, and to locations where large numbers of American Indians or Alaska Natives reside. Unless otherwise indicated, *Indian* refers to members of American Indian tribes, Alaska Native villages, and their descendants.

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Higher Education Consortium (AIHEC). In addition, most tribes and Alaska Native villages are members of consortia or regional organizations such as Bristol Bay Native Corporation and the Tanana Chiefs Conference in Alaska, the United South and Eastern Tribes (USET), the All Indian Pueblo Council (AIPC), and the Southern California Tribal Chairman's Association (SCTCA).

Federal Agencies Sponsoring Research in Indian Country

Occasionally Congress mandates studies and other forms of research in Indian Country; however, the bulk of the research is procured by or conducted by federal agencies. Most of this research is guided by each agency's mission and goals; in addition, some research is conducted to meet the requirements of the Government Performance and Results Act (GPRA) of 1993 that requires strategic planning and annual program performance reporting for every federal agency. In passing GPRA, Congress sought improved accountability for program performance and better planning of federal programs. GPRA has resulted in increased evaluation and other research to demonstrate program results.

Federal agencies that have conducted or sponsored the greatest amount of research in Indian Country include the Department of Health and Human Services (DHHS), the Bureau of Indian Affairs (BIA), the Department of Justice (DOJ), and the Department of Education (ED). Among these agencies, DHHS sponsors the greatest amount of research. Within DHHS, research is funded by the Indian Health Service (IHS), the National Institutes of Health (NIH), the Substance Abuse and Mental Health Services Administration (SAMHSA—which includes the Centers for Substance Abuse Treatment [CSAT], the Center for Substance Abuse Prevention [CSAP], and the Center for Mental Health Services [CMHS]), the Centers for Disease Control (CDC), the Administration for Native Americans (ANA), and the Administration for Children and Families (ACF).

In the last 10 years, DOJ has become increasingly active in promoting research in Indian Country. Within DOJ, agencies active in conducting or funding research include the Office of Justice Programs (OJP), which includes the National Institute of Justice (NIJ), the Drug Courts Program Office, and the Office of Juvenile Justice and Delinquency Prevention. Educational research in Indian Country is funded by both the BIA and ED. Other federal agencies that sponsor research in Indian Country include the Departments of Labor (DOL), Housing and Urban Development (HUD), Commerce (DOC), and Transportation (DOT).

Increasingly, but slowly, federal sponsors of research have begun to consult with tribes and tribal organizations in setting the agendas and guidelines for research to be conducted in Indian Country. Congress and federal agencies are soliciting input from tribes and tribal organizations with respect to research goals and research budgets. Some examples of agencies would be:

National Indian Health Board
http://www.nihb.org/inside_budget.htm

National Congress of American Indians
http://www.ncai.org/main/pages/legislative_updates/index.asp

United South and Eastern Tribes, Inc.
http://usetinc.org/resolutions.html

National Indian Education Association
http://www.niea.org/2001niearesos.pdf

Tribes and tribal organizations track proposed legislation and provide information to congressional representatives and their staffs and to congressional committees. Federal agencies often require researchers to establish project advisory committees that include tribal officials and experts on related research in Indian Country.

Nature of Research Conducted in Indian Country

The full range of research activities occurs in Indian Country, including randomized experiments, clinical trials, field experiments, quasi-experimental research, retrospective and prospective studies, cross-sectional and longitudinal studies, survey research, feasibility studies, evaluation research (including outcome, impact, and process evaluations), ethnographic research, participant observation, and case studies. The types of research conducted in Indian Country are not distributed evenly across sponsoring agencies. Most of the randomized experiments and clinical trials are conducted under the auspices of the NIH. For methodological (e.g., sampling) and logistical reasons, most research takes the form of evaluations, particularly process evaluations, feasibility studies, and case studies.

Sampling issues are especially problematic for research in Indian Country because of an implicit political dimension—the heart of sampling involves the selection of a subset of a defined universe or population. As a rule, it is not practical to define the universe population of interest as "members of all Indian tribes" or "all Indians" because there are over 550 federally recognized tribes, and there is great variation across tribes—variation in language, culture, location, economy, and a host of other factors. Thus, some researchers have discovered something that eludes many non-Indian people—American Indians are not a homogeneous group; rather, most are members of unique tribes. Compounding the sampling problem is the large American Indian diaspora—more Indians reside in cities and other off-reservation locations than on or near reservations and other tribal lands (Hillabrant, Romano, & Stang, 1992). Because of the great diversity across tribes in many domains, research findings obtained at one tribe, or on a group of tribes, may not be representative of other tribes. To plan and draw a representative (i.e., random) sample of American Indians and/or Alaska Natives residing on or near tribal lands would be a daunting task, beyond the means and resources of most research projects. Identifying a sample frame and drawing a representative sample from a single tribe or a group of tribes often presents problems that challenge the resources available to most research projects. Data commonly used to identify primary sampling units are often incomplete or unavailable. For example, many individuals may reside in dwellings without a published address or even a named street, lack Social Security numbers or telephones, may have multiple residences, and may be away from their primary residence for long periods of time fishing, hunting, trapping, and gathering/harvesting. Many of these challenges can be attenuated and managed through close collaboration with tribal officials and residents of the communities participating in the research.

Of course, it is possible to draw random, stratified random, probability proportionate to size, and multistage samples of well-defined groups in Indian Country. For example, a prospective study of substance abuse treatment outcomes included a first stage selection of 22 treatment facilities probability proportionate to size (number of clients served the prior year) within strata (IHS Areas), and quota samples of all clients accepted for treatment at randomly determined start dates (Hillabrant, Earp, & Rhoades, 2001). In a retrospective study of youth residential substance abuse treatment facilities, random samples of client records were selected for review at each of nine facilities (Hillabrant, Earp, & Brutus, 1997). An assessment of the expected impact of a change in the rule governing eligibility for services from the IHS included a random sample of the IHS user population—all IHS beneficiaries using an IHS or tribal facility in the last 3 years (Hillabrant, Earp, & Brutus, 1996). In this study, the sample frame was defined by automated patient registration and utilization data.

Emerging Tribal Influence on Research in Indian Country

Over the last 25 years, tribes, Native villages, and consortia have taken an increasingly active role in controlling research conducted in Indian Country. This active stance reflects the increasing autonomy exercised by tribes in taking control over programs such as education, the provision of health care services, employment, training programs, and welfare programs formerly operated by federal agencies. With the enactment of the Indian Self-Determination and Education Assistance Act (ISDEAA) of 1975 (Pub. L. 93-638), tribes began to exercise ever-increasing levels of control over programs, policies, and research affecting their members.

The increase in tribal control of research has been abetted by federal regulations requiring protection of people participating in research (21CFR Part 56). These regulations require that all research involving human participants be reviewed and approved by an institutional review board (IRB). Now, some tribes have constituted their own IRBs, which review all research conducted on or near the reservation in which tribal members are participants in the research. Regardless of whether or not a tribe has instituted an IRB, tribal approval is required for any research conducted on tribal lands.

The concern about protection of people participating in research, in turn, reflects revelation of unethical research in which participants were not informed about the risks involved or were deprived of treatment and care that could have saved their lives or ameliorated their conditions. Among the most publicized unethical research are 1) a study sponsored by the U.S. Public Health Service in which 400 African American men in Macon County, Georgia, were deprived of medication to cure syphilis and not told of their illness, putting others at risk of contracting the disease (Tuskegee Study); 2) a study conducted by the U.S. Army in which soldiers were given the drug LSD; and 3) studies where prison inmates and terminally ill patients received injections of cancer cells to study the response of their immune systems (Lemonick & Goldstein, 2002).

Overcoming History of Exclusion from Control of Research

In the 1800's, often after successful military campaigns and other conflicts with American Indians, the United States treated Indian people as wards of the federal government (*Cherokee Nation v. Georgia*, 1831; American Indian Policy Review Commission, 1997). In this trustee capacity, federal agencies, often acting through the BIA and, later, the IHS (with respect to health care), determined what research would be conducted, which tribes would participate in the research, and which tribal members would serve as research participants. While the legacy of this trustee relationship still reverberates today, tribes have increasingly expanded their sovereign control over programs affecting their members since the passage of ISDEAA in 1975. Because of a long history of exploitation and both benign and hostile neglect by the United States, many tribes and tribal organizations want to be involved in all aspects of research in Indian Country, including planning, design, data collection, reporting of, and dissemination of research findings. Tribes and tribal organizations are requiring that researchers 1) hire tribal members to assist in data collection and other research activities; 2) demonstrate how the research findings will benefit the tribe and tribal members; 3) guarantee that the research protocol does no harm to the tribe, tribal members, and the environment; 4) guarantee confidentiality or anonymity of research participants, tribal communities, and the tribe; and 5) publish results only after review and approval of the manuscript by tribal representatives (see e.g., American Indian Policy Review Commission, 1997). These requirements and limitations increasingly exercised by tribes can both benefit and impede research in Indian Country.

1. ***Hire tribal members.*** Requiring researchers to hire tribal members to assist in research activities can have several benefits. Such hiring increases employment and contributes to the tribal economy. Tribal members assisting with the research acquire skills and knowledge. Having tribal members participate on the research team is associated with other benefits, including:

   a. The research team is less likely to exploit research participants, expose them to unnecessary risk, or demean them.
   b. Researchers are less likely to employ or express invalid stereotypes, or to express, explicitly or implicitly, prejudicial perceptions, opinions, or expectations.
   c. Often, the quality of the data collected is improved because of enhanced communication and better rapport between the researchers and the study participants.

On the other hand, employing tribal members on the study team may be associated with a variety of costs. Hiring, training, and using tribal members on a research team can increase both the time required to complete the project and project costs. Using tribal members to collect data can create special problems for study participant confidentiality, and change the demand characteristics of the research (Orne, 1962). Study participants may conceal taboo or socially undesirable expectations, beliefs, or behaviors from other tribal members; such expectations, beliefs, or behaviors might be less concealed from outside investigators whom the research participants are unlikely to encounter in the future.

2. ***Demonstrate how the research findings will benefit the tribe and tribal members.*** It is customary for researchers to describe the anticipated benefits (and costs) of the research, especially in preparing grant proposals and in submissions to IRBs and OMB. Prior to the emergence of tribal control of research, discussions of the anticipated benefits of research in Indian Country tended to be abstract, making reference to Indians in general rather than to the participating tribe or tribes. Requiring researchers to relate costs and benefits to the participating tribe(s) tends to clarify thinking and make assumptions and expectations explicit—results often beneficial to the proposed research, the researcher, the participating tribe, and other stakeholders.

On the other hand, research in Indian Country, like research everywhere, is conducted in a social and political context. The perceived benefits and costs associated with a particular study may vary across stakeholders. For example, managers of tribal programs may perceive costs and benefits of a study differently from members of the tribal judiciary or legislature. Proponents of traditional values and approaches may differ from advocates of change. While involvement of tribal stakeholders with conflicting values, agendas, or perspectives can improve the robustness and acceptance of a study, such involvement can also mire the research in conflict, leading to disorganization or even abandonment of the research. Depending on their interests, stakeholders may embrace or repudiate research findings (see Vignette 1).

3. ***Guarantee that the research activity does no harm to the tribe, tribal members, and the environment.*** The level of risk to study participants, the tribe, and the environment and the potential to do harm depend on the nature of the research, with medical clinical research often bearing the greatest risk of harm to participants. However, risk is not limited to medical research, and all research has costs, even if only opportunity costs—time and resources spent on the research activity could be spent on alternative activities. Opportunity costs are especially important in situations where there are significant unmet needs, as is the case in much of Indian Country. Critics of research, including members of tribal IRBs, have suggested that most research funds would be better spent on service delivery. Of course, such judgments should consider the relative costs and benefits of a research project. It is the responsibility of the research sponsor(s) and those conducting the research to present

Vignette 1. Repudiation of unpopular results: Evaluation of the IHS Fiscal Intermediary (FI)

The IHS commissioned an independent evaluation of the performance of the FI in order to determine the degree to which the FI was achieving the goals and objectives specified in its contract. These responsibilities included 1) receiving bills and claims submitted by hospitals, clinics, and other providers outside of the IHS; 2) reviewing the claims to ensure conformance with treatment referrals and authorizations; 3) paying the valid claims and bills; and 4) producing reports of the services provided and amounts paid.

The evaluation was commissioned in the context of strong and ongoing criticism of the FI by staff in IHS and tribal clinics and by tribal officials. The major complaint about the FI was that it failed to pay bona fide claims within the 45-day time frame mandated by its contract with the IHS. Tribal officials were especially frustrated because providers submitted unpaid bills and claims to collection agencies. In turn, collection agencies hounded tribal members for payment of the claims unpaid by the FI.

Site visits to the FI and to IHS and tribal clinics conducted as part of the evaluation produced convincing evidence that the primary causes for the delayed payments were incomplete referrals and treatment authorizations submitted by clinic staffs. As a rule, when the FI received complete and valid information from clinics, it paid the claims in a timely fashion. The evaluation recommended a number of ways that the referrals and authorizations submitted by the clinics could be improved. The evaluation results were accepted by many stakeholders; however, some, hoping that the study results could be used to terminate the FI contract, repudiated the findings and ardently tried to suppress them (Hillabrant, Brown, Weller, & Earp, 1988).

the costs and benefits clearly to the tribe, the IRBs, OMB, and the study participants. It is the responsibility of the tribe, IRBs, and OMB to determine if the benefits outweigh the risks, that the risks do not exceed acceptable limits, and that participants are not exposed to unnecessary risks (see Vignette 2).

There are subtle aspects to the "do no harm" dictum for research in Indian Country. Many consumers of research in Indian Country may be ignorant of 1) the history of exploitation and discrimination faced by Indian tribes, communities, and individuals; 2) the circumstances of many tribes (e.g., remote location, weather extremes, lack of infrastructure); and 3) the legal and constitutional status of tribes. Without knowledge of these circumstances, such consumers are unlikely to appreciate the significance of research

Vignette 2. Risks involved in a screening feasibility study

Three tribes agreed to participate in a study to demonstrate the feasibility of a self-administered, multimedia, computer-assisted screening system to identify adolescents who 1) are victims of physical or sex abuse, 2) suffer from posttraumatic stress syndrome (PTSD), and 3) abuse alcohol and other drugs. The system was to be set up at tribal clinics providing primary care to tribal members; adolescents coming to the clinic for care would be recruited to participate in the feasibility study. All screening research includes the risk of two errors: 1) a *false positive* error occurs when the screening system indicates that the adolescent has been abused, traumatized, or involved in substance abuse when, in fact, no abuse, trauma, or substance abuse has occurred, and 2) a *false negative* error occurs when the screening system fails to detect abuse, trauma, or substance abuse when one or more, in fact, occurred. In addition, other risks associated with the proposed screening included 1) mental health/emotional crisis or problems associated with "hits" (correct detection by the screening system), and 2) adverse consequences should the health care delivery, child protection, or other systems fail to provide services needed by adolescents successfully identified by the screening.

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findings. While such factors are too numerous to list, several favorites of the author include:

- The unique circumstances of Alaska. Many if not most of the people who have never visited Alaska do not understand that it is farther from Anchorage to half-way through the Aleutian Islands than from Washington, DC to San Francisco, CA. Most Alaska Native villages have a single, unpaved road with an airstrip at one end. While there may be 20 trucks and cars in the village, they can leave the road only in winter when the tundra, lakes, and rivers freeze hard.
- Many residences in Indian Country lack electricity, telephones, and running water.
- For over 100 years, to the present day, the United States has been unable to account for money and resources held in trust for tribes and individual Indians.
- Tribes are explicitly mentioned in Article I, Section 8 of the U.S. Constitution (restricts to Congress the power to regulate commerce with the tribes), and citizenship was not conferred on American Indians until 1924, with the passage of the Indian Citizenship Act of 1924.
- Starting in the late 1800s, some Indian children were forced to leave their families to attend BIA boarding schools, where non-Indians prescribed the language they spoke, the religion they practiced, and the material they studied. Growing up apart from their families, frequently subjected to what is now (and often then) seen as physical and emotional abuse, had multiple, cross-generational negative effects on these children, their families, and tribes. While some of these boarding schools still exist, forced separation of children from their families ended, for the most part, by the 1950s.

Because many consumers of research in Indian Country are ignorant of these and other important data, researchers often need to provide background information so that the research results can be understood in context.

4. *Guarantee confidentiality or anonymity of research participants, tribal communities, and the tribe.* Often, tribes do not object to the identification of the tribe or of tribal communities in research reports. Other times, especially when research is conducted on sensitive topics, a tribe may insist that the research report not identify the tribe or communities participating in the research. Protecting the privacy of research participants and keeping their identity anonymous can pose a special challenge for small tribes and communities. If the program being evaluated is small, it can be almost impossible to maintain the anonymity of key informants who provide relevant information (see Vignette 3). Breaches of confidentiality and identification of tribal communities by researchers, despite their agreement not to do so, have been the source of frustration and reactions against research by several tribes (William Freeman, personal communication, June 30, 1999).

5. *Publish results only after review and approval of the manuscript by tribal representatives.* This requirement is often imposed by prudent researchers as well as by tribes. By obtaining review and feedback from the appropriate tribal representatives (generally persons who are knowledgeable about the research topics), researchers can often identify errors or omissions which otherwise might go uncorrected. Thus, such review can improve the quality of research conducted in Indian Country.

Over the last five years, federal sponsors of research have begun to disseminate research findings to all federally recognized tribes, tribal consortia, and Indian organizations. Both the BIA and IHS maintain a "tribal leaders" database available to the public and used as a mailing list for disseminating research reports (see, for example, http://www.ihs.gov/AdminMngrResources_index.asp). Increasingly, research reports are being published on the World Wide Web, available to tribes and the public at large, such as the report from Hillabrant, Rhoades, Pindus, and Trutko, available at the U.S. Department of Health and

Vignette 3. Ethical problem: Substance abuse treatment center director "using"

As part of a national evaluation of substance abuse treatment outcomes, researchers visited 22 treatment programs in Indian Country. At one of the programs, a small facility with a few staff, several staff members told the research team that the program director had relapsed and was "drinking every day, but without becoming grossly inebriated." The staff said that while they did not directly observe the program director drinking, they noted changes in her behavior and claimed to smell alcohol on her breath.

When asked why they did not report this problem to the appropriate tribal authorities, the staff said that there was no one at the treatment facility who supervised the director, and each feared the loss of his or her job if they were to report the problem. Some staff wanted the researchers to pass on the information to tribal officials, but other staff, fearing reprisals, asked the researchers not to pass on the allegations to others. It seemed likely to the researchers that reporting the alleged drinking to tribal officials could not be done without compromising the confidentiality of some of the participants (project staff).

The researchers were unable to independently confirm or disconfirm the alleged drinking by the program director. Some staff said that the program director was able to "remain clean" during the two-day site visit. Alternatives considered by the researchers included ignoring the allegations made by the staff, confronting the program director with the allegations, or passing on the allegations to the office of the tribal chairman.

The members of the research team decided that they would not pass on to tribal officials the allegations made by the staff; rather, they would contact the agency sponsoring the study for guidance. Subsequently, the researchers contacted tribal officials and discovered that the treatment program director had already resigned (Hillabrant, Earp, & Rhoades, 2001).

Human Services website (http://aspe.hhs.gov/hsp/wtw-grants-eval98/tribal02/).

Participatory, Self-, and Empowerment Evaluation

Program evaluation is supposed to be an integral component of program administration and improvement. When the program goals and objectives are formulated or reformulated, the evaluation is to be designed to assess progress toward the goals and objectives, and the evaluation results are to be used to inform and guide reformulation of program goals, objectives, policies, and procedures. Too often, it seems, the evaluation plans are lost or ignored, the evaluation is perceived by program managers and staff as a distraction from their work, and the evaluation results do not have the desired impact on the program.

In reaction to the underutilization or improper utilization of program evaluation, there has been a growing interest in conducting evaluation research in ways that foster improvement and self-determination of organizations, communities, and tribes; this approach has been termed participatory or empowerment evaluation (Fetterman, 2000). Empowerment evaluation seeks to help people help themselves and improve their programs through self-evaluation, reflection, and capacity building. Program participants conduct their own evaluations with the aid of an outside evaluator who often serves as a coach or facilitator. Because of their unique political, cultural, and historical circumstances, Indian tribes may find the empowerment evaluation approach especially useful.

Approval Processes

Obtaining the required approvals for research, especially in the areas of health and education, can be a complex, lengthy, and expensive proposition. Often, there are three levels of review: IRBs, OMB, and tribal; each is discussed below.

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IRBs

Institutional review boards (IRBs) are authorized and required by federal regulations (Title 45, Part 46 of the Code of Federal Regulations [CFR]as well as 21 CFR Part 50, protection of human subjects; 21 CFR Part 56, institutional review boards). These regulations pertain to research sponsored by the Departments of Agriculture, Energy, Commerce, Housing and Urban Development, Justice, Defense, Education, Veterans Affairs, Health and Human Services, and Transportation, as well as to research sponsored by other federal agencies such as the National Aeronautics and Space Administration, Consumer Product Safety Commission, Agency for International Development, and the Environmental Protection Agency. The primary objective of IRBs is the protection of human research participants. This protection is all-encompassing, including physical and mental health. Interested readers are referred to the Office of Human Subjects Research in the DHHS National Institutes of Research (http://www.dvincitbt.com/ohsrsite).

Fundamental to the protection of research participants is the concept of "informed consent." Informed consent means that the study participant understands all the risks and rewards associated with participation in the research. This understanding is to be conveyed to the research participants by the research staff in language that the participant can fully understand. The research participant must indicate his or her understanding of the risks and rewards associated with the research by signing an informed consent form, and the researchers are required to maintain the original forms while the research is being conducted.

In Indian Country, there may be multiple levels of IRB review, including national (agency-wide), area or region, and tribal. While it is possible to submit applications simultaneously to national and area or regional IRBs, it is not uncommon for one group or the other to require the prior approval of the other before completing their review. Since the IRB may meet only once each quarter, obtaining the necessary IRB approval may take one year or more, especially when one of the IRBs requires changes in study protocols, procedures, or data collection instruments. Some IRBs require the principal investigator to make a presentation to the board and to answer questions. Prudent researchers include the costs of such presentations in their budgets and project timelines.

Obtaining informed consent for research in Indian Country involves special challenges. The researcher must be sensitive to the ways that culture affects the participant's understanding and interpretation of the study. Some cultural components may seem relatively obvious, such as the need for presentation of the information in the participant's primary language; however, the difficulties in translation are often revealed by heated discussions among translators as to what expression or metaphor should be used to communicate key concepts or aspects of the research. Other cultural components that affect obtaining informed consent and other aspects of research in Indian Country might include:

- Norms about the expression of disagreement or conflict;
- Kinship systems, the perception of how individuals are related, and norms governing interaction among related individuals;
- Childrearing practices and associated norms and expectations; and
- Models of health and disease and associated norms, expectations, attributions, and perceptions.

Cultural factors that are unknown to the researchers can wreak havoc with research—"it's what you don't know that can really hurt you." One approach to identifying cultural factors likely to affect a study is the use of an advisory committee that includes key informants from the community or communities participating in the research, as advocated by other authors in this monograph. Even with such an advisory committee, unexpected cultural factors can damage research. In an IHS-sponsored national

evaluation of substance abuse treatment outcomes for American Indian and Alaska Native women, no data were obtained from one tribal treatment program because most women served by the program refused to participate in the study. Many of these women were angry because 1) they had been forced to enter into treatment by a judicial proceeding, and 2) men were not required (or allowed) to participate in the study. While these circumstances were not unique to the tribe in question, they interacted with the unique aspects of the tribe's culture pertaining to gender roles; the other 21 tribal programs in the study successfully recruited into the study women in similar circumstances (Hillabrant, Earp, & Rhoades, 2001).

Another aspect of research participant protection is the maintenance of confidentiality of participant data. Researchers must demonstrate to the IRB that no one, except the researchers, will be able to obtain or infer information about individual participants collected during the research. Researchers working in the area of substance abuse can face special challenges to maintaining participant confidentiality. Because substance abuse can include the use of illegal drugs (e.g., marijuana, cocaine, heroin, or the use of prescription drugs without a legitimate prescription), law enforcement officials may request study data and, in particular, the names of research participants who use illegal drugs. Such requests can come in the form of a subpoena issued by a court.

A *Certificate of Confidentiality*, issued by the National Institute on Alcohol Abuse and Alcoholism (NIAAA), authorizes researchers to withhold the names and other identifying characteristics of people who participate as subjects in the research project specified in the certificate. This authorization applies to all persons who, in the performance of their duties in connection with the research project, have access to information that would identify the subjects of that research. Persons so authorized may not, at any time, be compelled to provide the names or other identifying characteristics of the research participants encompassed by the certificate in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The statutory authority for the certificate of confidentiality is section 301(d) of the Public Health Service Act (part USC 241 [d]). The applicable regulations are set forth at 42 CFR Part 2a.

OMB Review

The Paperwork Reduction Act of 1995 requires that the Office of Management and Budget (OMB) review and approve all federally sponsored research, other than grants, that includes more than nine individuals. The materials are submitted to the OMB by the funding federal agency; however, contractors and researchers often draft the "OMB submission package" for the client agency. The OMB package includes:

- Justification of the research, including proposed use of the study findings;
- Explanation of information technology used to promote efficiency and reduce the burden of the research participants;
- Explanation of how participant confidentiality will be assured;
- Estimates of burden on research participants and cost of the research;
- Project schedule and publication plans;
- Statistical methods to be used (generally includes sample design, research design, and planned analyses);
- Notices describing the study to be published in the *Federal Register*.

The process of preparing the OMB submission package, responding to questions raised by the OMB, and obtaining the required approval or clearance generally requires 6-12 months. In the past, some agencies have taken the stance that research conducted in Indian Country is exempt from OMB review because of tribal sovereignty. The position taken is that the research is being conducted on behalf of the tribes, and the tribes are not subject to the Paperwork Reduction Act. Such research has

proceeded without obtaining an OMB clearance number and, presumably, without OMB's knowledge.

Tribal Approval

Whether or not a tribe operates an IRB, research on tribal lands requires tribal approval. If the tribe has delegated responsibility for review and approval of research proposals to an agency or office, the review process is greatly simplified. If no such delegation exists, the tribal council, business committee, or other group reviews the research proposal; such review can be a lengthy process. The approval process can be expedited, and the quality of the research improved, if the researchers identify and persuade stakeholders at the tribe of the merits of the study.

An advocate for the research who works for or with each tribe can make the difference between a long review process ending in disapproval, and an expedited, successful review. For example, one tribe approved its participation in the national welfare-to-work (WtW) evaluation within four weeks and approved participation in the women's substance abuse treatment outcome study only after two years of deliberations (Hillabrant, Rhoades, Pindus, & Trutko, 2001; Hillabrant, Earp, & Rhoades, 2001). While the two studies varied across many dimensions, two critical factors seemed to account for the difference in speed of approvals: 1) approval of the tribal IRB was required in the treatment outcome but not in the WtW evaluation, and 2) the WtW evaluation had the strong support of key stakeholders (heads of tribal departments) whereas the treatment outcome study lacked a strong advocate at the tribe. Interestingly, the treatment outcome study was supported by some stakeholders; the substance abuse treatment programs supported the study, but corresponding support was lacking among stakeholders with the needed "influence."

Sometimes stakeholders at tribes are enthusiastic about participating in a research project because they want to share successful approaches with other tribes. For example, in a study of family violence in Indian Country, one tribe had developed a model approach that included legislation identifying family violence as an offense and implementation of effective policies and procedures for tribal police and courts—mandatory arrest of perpetrators, use of male-female police teams responding to family violence complaints (Hillabrant, Brown, Colhoff, & Earp, 1994). In the WtW evaluation, a tribe had developed a model approach to child support enforcement (CSE) which involved close collaboration with states to identify noncustodial parents who were employed but were not providing support for their children and to garnishee the wages of persons who refused to comply with tribal court orders to provide child support (Hillabrant, Rhoades, Pindus, & Trutko, 2001).

Longitudinal research and studies that involve data collection for six months or more can face additional problems including changes in tribal administration and changes in program staffing. Changes in tribal administration (e.g., new chairman, chief, governor) or newly elected tribal council members may view with suspicion research approved by a prior administration. Soliciting and obtaining approval of proposed research from a wide range of stakeholders can circumvent or minimize the effects of changes in administration. Effects of changes in program staffing on a study can range from minimal to catastrophic, depending on the nature of the research. Frequently, new staff must be trained to use or interface with the study protocol.

Ethical Problems and Issues

In general, research in Indian Country may have neither more nor fewer ethical problems and dilemmas than research conducted elsewhere. Still, issues such as cultural competence, relatively high rates of poverty and illness, and associated deficits in infrastructure (e.g., public transportation, plants and facilities, telecommunications) can exacerbate ethical problems and dilemmas.

University graduate training programs teaching research ethics may cover federal regulations and procedures associated with IRBs and OMB as well as regulations governing the care of animals in research (Health Research Extension Act of 1985); however, it is difficult for such training to focus on ethical issues and problems associated with persons who might come into contact with the research but who are not participants. Also, it is difficult for ethics training to address problems where the researcher's actions must balance immediate costs against potential greater costs. This paper concludes with discussion of such a problem.

Already discussed in Vignette 3 is the allegation of on-the-job substance abuse by a treatment program director. Another example involves the evaluation of a Head Start program producing exceptional benefits that was housed in a building that represented unacceptable risks to the children it served (see Vignette 4). The evaluators were confronted with the choice of reporting the violations, likely to result in the suspension of the program, or passively acquiescing in the continued exposure of the children to the risks associated with an unsafe building.

Making judgments about ethics and values can be challenging to researchers working in Indian Country because of potentially conflicting roles and circumstances, such as:

- If the researcher is not a member of the tribe participating in the study, he or she may be unfamiliar with critical values and expectations pertaining to ethical issues.
- The sponsor of the research may have agendas, rules, and expectations that are different from or in conflict with those of the tribe(s) participating in the study.
- The protection of study participant confidentiality may conflict with protection of study participants from abuse, family violence, or other threats.

In such circumstances, it is prudent for the researcher to seek guidance from the project advisory committee, the research sponsor, and/or legal authorities without disclosing information that would violate the identity of the research participant(s) or violate the confidentiality of participant data.

Vignette 4. Ethical problem: Closing an excellent Head Start facility.

The national Head Start program conducts rolling compliance reviews of local Head Start facilities to ensure that the programs protect the health and welfare of the children served. One of the program requirements is that no Head Start facility be located in a building with major building code violations. Conducting site visits at several facilities on a reservation, researchers found, with one exception, that each facility met or exceeded all Head Start program requirements. The children attending these programs were clearly flourishing, and entire families were benefiting from the program. One facility, however, was located on the second story of a wooden building that had multiple building code violations, including insufficient numbers of fire extinguishers and smoke detectors. Program staff were aware of the code violations; however, there were few alternate facilities available on the reservation that could be used by the Head Start program, and tribal officials had not responded to requests for better facilities.

The researchers did not want to jeopardize the operation of the clearly successful program. Options discussed included ignoring the code violations, urging program staff to continue their efforts to secure an alternate facility, and reporting the infractions to Head Start headquarters in Washington.

After a brief discussion, the study team concluded that failure to act, in this case, would subject the children participating in the program to unacceptable risks. Consultation with Head Start headquarters resulted in an order that the tribe immediately suspend operation of the program at the dangerous facility. This suspension stimulated tribal officials to action. Within a week, the tribe was able to make available a building that complied with Head Start regulations and the program resumed operations.

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